Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Use of galactogogues in initiating or augmenting the rate of maternal milk secretion.

Bibliographic Source(s)

Academy of Breastfeeding Medicine Protocol Committee. ABM clinical protocol #9: use of galactogogues in initiating or augmenting the rate of maternal milk secretion. Breastfeed Med. 2011 Feb;6(1):41-9. [65 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Academy of Breastfeeding Medicine. Use of galactogogues in initiating or augmenting maternal milk supply. New Rochelle (NY): Academy of Breastfeeding Medicine; 2004 Jul 30. 5 p.

Academy of Breastfeeding Medicine (ABM) protocols expire five years from the date of publication. Evidence-based revisions are made within 5 years or sooner if there are significant changes in the evidence.

Recommendations

Major Recommendations

Practice Recommendations

The following recommendations, based upon current evidence, apply to women experiencing difficulties with a low rate of milk production (e.g., the baby is not gaining weight normally or supplementation is being used because of low milk production, during either the initiation or maintenance of milk supply).

Specific information about individual drugs and herbs is summarized at the end of these recommendations in the Appendix in the original guideline document.

1. Evaluate and augment the frequency and thoroughness of milk removal. Use non-pharmacologic measures to increase the overall rate of breast milk synthesis.
    - For women with healthy term infants: Improve breastfeeding practices (*Level of Evidence I*).
        - Recommend skin-to-skin contact between mother and baby to facilitate frequent feeding and stimulate oxytocin release (the milk ejection reflex [MER]) (Uvnas-Moberg, 2003).
        - Encourage mother to perform self-breast massage in order to improve oxytocin release (MER) and milk removal.
        - Review or teach relaxation techniques to facilitate oxytocin release (MER) for improved milk removal.

- Help the mother–infant dyad to achieve optimal latch-on (Anderson & Valdes, 2007; Sakha & Behbahan, 2008; Seema, Patwari, & Satyanarayana, 1997).
- Resolve nipple pain, if applicable, using the following strategies:
  - Optimal latch-on
  - Diagnosis and management of other causes of pain
  - Refer to a lactation specialist as needed
- Emphasize unrestricted frequency and duration of breastfeeding (if the infant has been shown to be effectively transferring milk) (Sakha & Behbahan, 2008; Seema, Patwari & Satyanarayana, 1997).
- Advise the mother to reduce or stop unnecessary supplementation (Academy of Breastfeeding Medicine [ABM] Protocol Committee, 2009) and provide strategies for how to do so.
  - Gradual tapering off of amounts of supplementation
  - Use of "supplementer system" (tube at the breast attached to a source of supplemental milk) if appropriate.

- For women with babies who are ineffective at milk removal or unable to feed at the breast (e.g., premature, hospitalized, hypotonic):
  - Recommend and teach gentle hand expression of colostrum: The volume extracted by hand expression is greater than the volume extracted by full size, automatic cycling breast pumps (Ohyama, Watabe, & Hayasaka, 2010); video and photographic illustrations of hand expression are available at newborns.stanford.edu/Breastfeeding/HandExpression.html (Morton, 2010) and www.breastfeeding.com/helpme/helpme_images_expression.html ("Expressing breastmilk," 2010).
  - Recommend milk expression with a full-size, automatic cycling breast pump, capable of draining both breasts at the same time ("hospital grade"), if available (*Level of Evidence II-2*) (Green et al., 1982).
  - Recommend "hands-on pumping" (a combination of hand expression with double pumping); this technique was superior to double pumping alone in one randomized, controlled trial (Jones, Dimmock, & Spencer, 2001) and one observational study (Morton et al., 2009) (*Level of Evidence I and II-3*).
  - Recommend that women adjust the electric pump to their maximum comfortable vacuum, which enhances milk flow rate and milk yield and minimizes occurrence of tissue damage (*Level of Evidence II-1*) (Kent et al., 2008).
  - Recommend hand expression if a hospital-grade pump is not available or if the woman prefers the manual technique; hand expression requires instruction and a period of practice until the mother becomes proficient.
  - Foot pump expression does not require electricity and may be another available alternative (Becker, McCormick, & Renfrew, 2008).

2. Evaluate the mother for "medical" causes of hypogalactia: Pregnancy, medications, primary mammary glandular insufficiency, breast surgery, polycystic ovary syndrome, hypothyroidism, retained placenta, theca lutein cyst, loss of prolactin secretion following postpartum hemorrhage, heavy smoking or alcohol use, or other pertinent conditions. Treat the condition as indicated, if treatment is available (Lawrence & Lawrence, 2005) (*Level of Evidence II-2, II-3, and III*).
3. Because current research of all galactogogues is relatively inconclusive and all of the agents have potential adverse effects, Academy of Breastfeeding Medicine (ABM) cannot recommend any specific pharmacologic or herbal galactogogues at this time.
4. The healthcare provider who weighs the potential risks versus the potential benefits of these agents and chooses to prescribe a galactogogue should follow the guidelines below (*Level of Evidence III*) (see the Appendix in the original guideline document regarding details of prescribing specific galactogogues).
5. Inform women about available data concerning efficacy, timing of use, and duration of therapy of galactogogues (*Level of Evidence I*) (Anderson & Valdes, 2007). (Specific information is presented in the Appendix of the original guideline document.)
6. Inform women about available data concerning potential adverse effects of galactogogues (see the Appendix in the original guideline document regarding details of specific galactogogues):
   - Screen the mother for allergies to, contraindications to, or drug interactions with the chosen medication or other substance.
   - Provide ongoing care to, supervise ongoing care of, or transfer care of both mother and infant to ensure appropriate follow-up and attention to any side effects.
   - Prescribe galactogogues at the lowest possible doses for the shortest period of time; do not exceed recommended therapeutic doses.
   - Consider gradually discontinuing the drug (tapering the dose) at the end of therapy; some studies stop the drug at the conclusion of therapy, and others gradually discontinue the drug, with no clear advantage to either method.
   - If milk production wanes after stopping the drug and improves again with resumption of the medication, attempt to gradually decrease the drug to the lowest effective dose and then discontinue the drug at a later date if possible.
   - Consider obtaining written documentation of informed consent when using any galactogogues.

Definitions:

Levels of Evidence

I Evidence obtained from at least one properly randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports; or reports of expert committees.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Maternal milk production

Guideline Category

Counseling

Evaluation

Management

Treatment

Clinical Specialty

Family Practice

Nursing

Nutrition

Obstetrics and Gynecology

Pediatrics

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To facilitate optimal breastfeeding
- To provide recommendations on the use of galactogogues in initiating or augmenting maternal milk supply
- To develop clinical protocols for managing common medical problems that may impact breastfeeding success

Target Population

Women experiencing difficulties with a low rate of milk production

Interventions and Practices Considered

Evaluation/Management

1. Evaluate and augment the frequency and thoroughness of milk removal
2. Counsel women on improving breastfeeding practices
3. Evaluate the mother for "medical" causes of hypogalactia
4. Inform women about the efficacy, safety, and timing of use of galactogogues
5. Inform women about available data concerning potential adverse effects of galactogogues
    - Screen mother for allergies or other contraindications
    - Provide ongoing support and follow-up to mother and infant
    - Prescribe galactogogues at lowest possible doses for shortest periods of time
    - Obtain informed consent when using galactogogues

Major Outcomes Considered

- Maternal milk supply
- Adverse events associated with the use of galactogogues

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An initial search of relevant published articles written in English in the past 20 years in the fields of medicine, psychiatry, psychology, and basic biological science is undertaken for a particular topic. Once the articles are gathered, the papers are evaluated for scientific accuracy and significance. For the 2010 update, searches were performed that included August 2009 through December 2010, in order to add articles written from 2004-2010.

The databases searched included: Medline, Cochrane Database/Libraries, ProQuest Nursing & Allied Health Source and Web of Science. The search terms included: breastfeeding, breast-feeding, breast feeding, milk supply, milk production, milk synthesis, galactagogues, galactogogues, metoclopramide, domperidone, fenugreek, milk-thistle, blessed thistle, growth hormone, TSH, breast pump, oxytocin, prolactin, skin-to-skin.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

I Evidence obtained from at least one properly randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

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II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports; or reports of expert committees.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

An expert panel is identified and appointed to develop a draft protocol using evidence based methodology. An annotated bibliography (literature review), including salient gaps in the literature, are submitted by the expert panel to the Protocol Committee.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The draft protocol is peer reviewed by individuals outside of contributing author/expert panel, including specific review for international applicability. The Protocol Committee's sub-group of international experts recommends appropriate international reviewers. The Chair and/or protocol resource person institutes and facilitates this process. Reviews are submitted to the committee Chair and resource person.

The contributing author/expert panel and/or designated members of protocol committee work to amend the protocol as needed.

The draft protocol is submitted to the Academy of Breastfeeding Medicine (ABM) Board for review and approval. Comments for revision will be accepted for three weeks following submission. The Chair, resource person and protocol contributor(s) amend the protocol as needed.

Following all revisions, the protocol has the final review by original contributor(s) to make final suggestions and ascertain whether to maintain contributing authorship.

The final protocol is submitted to the Board of Directors of ABM for approval. A two-thirds majority of Board members' positive vote is required for final approval.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Academy of Breastfeeding Medicine Protocol Committee. ABM clinical protocol #3: hospital guidelines for the use of supplementary feedings in the healthy term breastfed neonate, revised 2009. Breastfeed Med. 2009 Sep;4(3):175-82. PubMed

Anderson PO, Valdes V. A critical review of pharmaceutical galactagogues. Breastfeed Med. 2007 Dec;2(4):229-42. [71 references] PubMed

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Green D, Moye L, Schreiner RL, Lemons JA. The relative efficacy of four methods of human milk expression. Early Hum Dev. 1982 Apr;6(2):153-9. PubMed

Jones E, Dimmock PW, Spencer SA. A randomised controlled trial to compare methods of milk expression after preterm delivery. Arch Dis Child Fetal Neonatal Ed. 2001 Sep;85(2):F91-5. PubMed

Kent JC, Mitoulas LR, Cregan MD, Geddes DT, Larsson M, Doherty DA, Hartmann PE. Importance of vacuum for breastmilk expression. Breastfeed Med. 2008 Mar;3(1):11-9. PubMed

Lawrence RA, Lawrence RM. Breastfeeding: A guide for the medical profession. 6th ed. Philadelphia (PA): Elsevier Mosby; 2005.

Morton J, Hall JY, Wong RJ, Thairu L, Benitz WE, Rhine WD. Combining hand techniques with electric pumping increases milk production in mothers of preterm infants. J Perinatol. 2009 Nov;29(11):757-64. PubMed

Morton J. Hand expression of breastmilk newborns. [Internet]. Palo Alto (CA): Stanford School of Medicine; [accessed 2010 Dec 03].

Ohyama M, Watabe H, Hayasaka Y. Manual expression and electric breast pumping in the first 48 h after delivery. Pediatr Int. 2010 Feb;52(1):39-43. PubMed

Sakha K, Behbahan AG. Training for perfect breastfeeding or metoclopramide: which one can promote lactation in nursing mothers. Breastfeed Med. 2008 Jun;3(2):120-3. PubMed

Seema, Patwari AK, Satyanarayana L. Relactation: an effective intervention to promote exclusive breastfeeding. J Trop Pediatr. 1997 Aug;43(4):213-6. PubMed

Uvnas-Moberg K. The Oxytocin factor. Cambridge (MA): Perseus Books; 2003.

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is stated for selected recommendations (see the "Major Recommendations" field).

The recommendations were based primarily on a comprehensive review of the existing literature. In cases where the literature does not appear conclusive, recommendations were based on the consensus opinion of the group of experts.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of galactogogues for initiating or augmenting maternal milk supply

Potential Harms

Adverse effects of galactogogues. See the Appendix of the original guideline document regarding details of specific galactogogues.

Qualifying Statements

Qualifying Statements

A central goal of the Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may impact breastfeeding success. These protocols serve only as guidelines for the care of breastfeeding mothers and infants and do not delineate an exclusive course of treatment or serve as standards of medical care. Variations in treatment may be appropriate according to the needs of an individual patient. These guidelines are not intended to be all-inclusive, but to provide a basic framework for physician education regarding breastfeeding.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2004 (revised 2011 Feb)

Guideline Developer(s)

Academy of Breastfeeding Medicine - Professional Association

Source(s) of Funding

Academy of Breastfeeding Medicine

This work was supported in part by a grant from the Maternal and Child Health Bureau, U.S. Department of Health and Human Services.

Guideline Committee

Academy of Breastfeeding Medicine Protocol Committee

Composition of Group That Authored the Guideline

Committee Members: Maya Bunik, M.D., MSPH, FABM; Caroline J. Chantry, M.D., FABM; Cynthia R. Howard, M.D., M.P.H., FABM; Ruth A. Lawrence, M.D., FABM; Kathleen A. Marinelli, M.D., FABM, (*Committee Chairperson*); Larry Noble, M.D., FABM, (*Translations*

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Financial Disclosures/Conflicts of Interest

Not stated

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Academy of Breastfeeding Medicine Web site .

Print copies: Available from the Academy of Breastfeeding Medicine, 140 Huguenot Street, 3rd floor, New Rochelle, New York 10801.

Availability of Companion Documents

The following is available:

- Procedure for protocol development. Academy of Breastfeeding Medicine. 2011 Mar. 2 p. Available from the Academy of Breastfeeding Medicine Web site .

Print copies: Available from the Academy of Breastfeeding Medicine, 140 Huguenot Street, 3rd floor, New Rochelle, New York 10801.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 1, 2007. The information was verified by the guideline developer on December 2, 2008. This summary was updated by ECRI Institute on April 1, 2009 following the FDA advisory on Reglan (metoclopramide). This NGC summary was updated by ECRI Institute on July 12, 2011.

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